

REMARKS

Independent claim 35 has been amended to include the feature of claim 49 to clarify that the claimed method is directed to producing a tissue graft and grafting the tissue formed on the molding support into a recipient. These amendments find support at least in paragraphs [0059], [0061], [0065], [0070], [0108], [0110] and [0179].

Claim 36 has been amended to clarify that the molding support is removed from the body cavity prior to grafting. This amendment is supported at least in paragraphs [0019], [0059], [0107], and [0108].

Claims 35-56 stand rejected under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over, any of Brauker, Moukheibir and Gosserez. Applicants respectfully assert that the cited references, whether alone or in combination, fail to teach or reasonably suggest the subject matter of the claims as amended.

Claim 35 has been amended to include grafting the tissue formed on the molding support into a recipient. Notwithstanding the rejection of all the claims in the final Office Action, the Examiner did not raise any specific rejection of claim 49. Brauke, Moukheibir, and Gosserez fail to disclose or suggest using non-vascularized tissue formed on a molding support that is placed within the body cavity for grafting into a recipient for the treatment or prophylaxis of diseased or damaged tissue.

Brauker discloses an implant material that results in close vascularization by the host at the interface between the material and the host into which the material is implanted. Brauker contemplates using the material (1) as a coating for indwelling catheters, (2) means for transport of physiological factors to indwelling sensors, (3) means for transport of drugs, chamber or catheter to the tissues of the host and (4) means for encapsulation of grafted cells for treatment of cell and molecular deficiency diseases (see column 3, lines 54-63). Significantly, Brauker is particularly concerned with promotion of vascularization and especially a vascular bed formed

immediately adjacent to the material-host interface. This means, therefore, that Brauker teaches away from forming non-vascularized tissue around a molding support for the purpose of grafting. Indeed, any tissue formed using the implant of Brauker could not be easily removed and grafted due to the vascularization formed immediately adjacent to the material-host interface.

Moukheibir involves a surgically implanted apparatus for subcutaneous placement in the body of a patient and by which peritoneal dialysis may be performed with lower risk of infection. This reference, however, is not concerned with forming non-vascularized tissue on a molding support and then grafting that tissue into a recipient.

Gosserez involves an implantable mammary prosthesis adapted to combat the formation around it of a retractile shell in reaction to a foreign body. Gosserez notes that in 20-30% of mammary implants over a period of months or years following implantation, a membrane that forms around the prosthesis due to a foreign body reaction, thickens and retracts to form a shell approximating the shape of a sphere to a greater or lesser degree. In attempting to limit the formation of such a membrane (i.e., non-vascularized tissue), Gosserez teaches a prosthesis of a certain shape/configuration that protects it from retraction. Gosserez, therefore, teaches away from the present invention in that it limits the formation of non-vascularized tissue around a molding support. Further, this reference neither teaches nor suggests removing any non-vascularized tissue and grafting it into a recipient.

Accordingly, none of the cited references teaches each and every element of the amended claims. As such, the claims as amended should be allowed over these references.

Additionally, none of the cited references is concerned with the production of tissue for grafting into recipients and, in fact, Brauker and Gosserez actively teach against the formation of non-vascularized tissue.

Significantly, therefore, the cited references do not teach or reasonably suggest the placing a molding support within the body cavity to form non-vascularized tissue on the molding support and to graft the non-vascularized so formed into a recipient.

For the foregoing reasons, the rejection of claims 35-56 as being anticipated by or, in the alternative, as obvious over, any of Brauker, Moukheibir and Gosserez should be withdrawn.

Claims 35-56 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,626,823. A terminal disclaimer accompanies this amendment. Accordingly, this rejection is not moot.

In the event the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Attorney Docket No. **229752001220**.

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